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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,603	07/01/2003	Colombe Chappey	11068-065-999	4793
20583	7550	12/23/2008	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			HUMPHREY, LOUISE WANG ZHIYING	
			ART UNIT	PAPER NUMBER
			16-48	
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			12/23/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/612,603

**Applicant(s)**

CHAPPEY ET AL.

**Examiner**

LOUISE HUMPHREY

**Art Unit**

1648

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 12, 13, 18, 21, 24, 25, 29, 31 and 39-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 12, 13, 18, 21, 24, 25, 29, 31 and 39-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This Office Action is in response to the amendment filed 19 September 2008. Claims 2-11, 14-17, 19, 20, 22, 23, 26-28, 30 and 32-38 have been cancelled. Claims 1, 12, 13, 18, 21, 24, 25, 29, 31 and 39-42 are pending and currently examined.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1, 12, 13, 18-21, 23-29, 31 and 36-42 under 35 U.S.C. §112, second paragraph, as being indefinite is withdrawn in response to the Applicants' amendment.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1, 12, 13, 18-21, 23-29, 31 and 36-42 under 35 U.S.C. §102(b) as being anticipated by Condra *et al.* (1996) is withdrawn in response to Applicant's amendment.

The rejection of claims 1, 12, 13, 18-21, 23-29, 31 and 36-42 under 35 U.S.C. §102(a) as being anticipated by Beerenwinkel *et al.* (June 2002) is withdrawn in response to Applicant's amendment.

The rejection of claims 1, 12, 13, 18-21, 23-29, 31 and 36-42 under 35 U.S.C. §102(b) as being anticipated by Paulsen *et al.* (11 June 2001) is withdrawn in response to Applicant's amendment.

### ***Response to Arguments***

The rejection of claims 1, 12, 13, 18, 21, 24, 25, 29, 31 and 39-42 under 35 U.S.C. §102(b) as being anticipated by Palmer *et al.* (1999, hereinafter "Palmer") is **maintained**.

The instant claims are directed to a method for determining whether a human immunodeficiency virus type 1 (HIV-1) has an increased likelihood of having a reduced susceptibility to treatment with amprenavir, comprising: detecting whether the protease encoded by said HIV-1 exhibits the presence of a mutation associated with reduced susceptibility to treatment with said protease inhibitor at amino acid position 11, 34, 47, 48, 50, 76, 83, 91 or 95 of an amino acid sequence of said protease, wherein the mutation at amino acid position 34 is Q, the mutation at amino acid position 43 is T, and wherein the presence of said mutation indicates that the HIV-1 has an increased likelihood of having reduced susceptibility to treatment with amprenavir, with the proviso that said mutation is not V32I, I47V, or I50V, and wherein the level of susceptibility,

mutations, and position number are compared to the protease sequence of the NL4-3 reference strain.

Applicant's arguments have been fully considered but are not persuasive. Applicant argues that Palmer reference does not teach in any way that any of the codons presently recited by the claims are significantly associated with amprenavir resistance. Examiner does not concur. Palmer teaches that mutation at position 48 of the HIV protease is known to cause resistance after protease inhibitor treatment. Amprenavir is a protease inhibitor, so Palmer teaches that mutation at position 48 of the HIV protease is significantly associated with amprenavir resistance. Besides, the wherein clauses are not given patentable weight because it does not materially affect the physical method step of detecting amino acid sequence mutation in the claimed invention. Palmer anticipates the instant invention so long as it teaches a method for determining the sequence of an HIV-1 strain and the resistant mutations such as G48V (Table 1 and Table 2).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 1, 12, 13, 18-21, 23-29, 31 and 36-42 under 35 U.S.C. §103(a) as being obvious over Kempf *et al.* (August 2001) is withdrawn in response to Applicants' amendment.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. H./  
Examiner, Art Unit 1648  
12 December 2008  
/Bruce Campell/  
Supervisory Patent Examiner, Art Unit 1648